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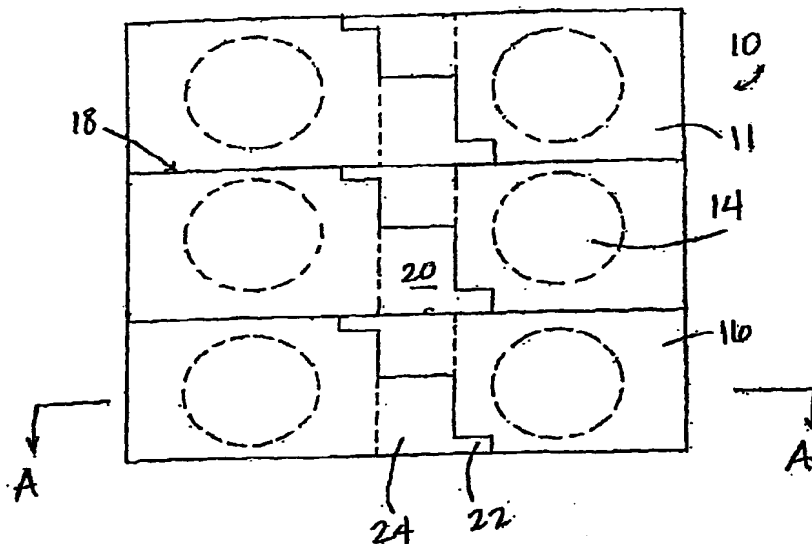
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[Continued on next page]

(54) Title: IMPROVED BLISTER PACKAGING



(57) Abstract: A packaging having a tray (12) having at least one recess to receive contents therein and an upper layer. The pack-
aging also has a manually removable sheet (16) that is fixed in part to the upper layer of the tray and unfixed in part to the tray, the
unfixed part of the sheet being in the form of a tab (20). The tab is located adjacent to one corner of the upper portion of the tray that
forms the recess, whereby when the sheet is fixed to the tray it is an effective seal against moisture and light. The packaging may
have a peel off layer that may be manually removed for those with limited dexterity. The tab has a graduated width for easy grasping
by the patient. The tray does not need to be separated into subsections prior to removal of the contents therein.



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IMPROVED BLISTER PACKAGING

5 CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Application No. 60/416,018, filed October 4, 2002, the entire disclosure of which is hereby incorporated herein by reference.

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TECHNICAL FIELD OF THE INVENTION

This invention relates to packaging of goods, such as tablets, capsules
15 or other solid pharmaceutical dosage forms. The package includes a lower tray for receiving such goods which are subsequently covered by a sheet which is sealed, in part, to the tray.

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BACKGROUND OF THE INVENTION

Blister-type packaging is one of the more common forms of packaging for solid pharmaceutical dosage forms, particularly in Europe where blister-type packaging is more common. Also, blister packaging is used for certain dosage
25 forms that cannot be exposed for any length of time to either moisture or light, or where the dosage form can be easily damaged.

In particular, blister-type packaging consists of a lower portion or "tray" which comprises a series of separate, spaced apart recesses. Each recess is
30 sized to be slightly larger than the solid dosage form. Each recess typically receives a single dosage form. The solid pharmaceutical dosage forms are then protected within the recess by sealing the exposed or upper portion of the tray with a sheet in whole or in part.

35 The sheet may include metal, such as aluminum, depending on the extent of protection needed by the particular solid pharmaceutical dosage form. The sealing is typically a heat sealing process. The sealing of the sheet onto the tray is designed to prevent moisture and light from getting into the recess.

CONFIRMATION COPY

Proper storage of solid dosage forms such as tablets and capsules is important in maintaining a level of quality for the stored product through the determined shelf life. If moisture and/or light get through to the dosage form, the shelf life of the dosage form may be significantly compromised, and the quality of the dosage form may be detrimentally effected. If this happens, the safety and/or efficacy of the dosage form may be compromised.

At present, the type of blister packs that require metallic laminates require a thick layer of the metal (in the range of 15 to 60 microns) to be effective. With this thickness, it then becomes difficult for the user to easily remove the tablet or capsule without damaging the tablet or capsule in the process in situations where the tablet or capsule is pushed through the aluminum layer. Thus, at present, many of existing metallic foil blister pack designs which effectively seal against moisture require the use of scissors to remove the metallic laminate seal from the recess in order to access the tablet or capsule. Patients having limited dexterity or strength, may not be able to safely remove the dosage form from the seal without significant risk to their safety. Moreover, even with the use of scissors or another sharp object, removal of the tablet or capsules intact also becomes a problem. Many tablets or capsules are not effective if taken when damaged. In addition, a scissors or knife or other sharp object is not always available for use, for example during air travel.

In addition to the thick metal layer, blister-type packaging at present often times requires the separation of the lower portion or tray into smaller subsections in order to access a tab or an unsealed edge from which to peel off the sealed layer. Again, the separation of the tray into subsections may cause damage to the dosage forms contained therein or result in an unintentional opening of one or more recesses during the separation process. Moreover, it may be difficult or impossible for patients with limited dexterity or strength to separate the tray into the subsections.

A further limitation on the blister-type packaging of today involves the location of the unsealed area of the sheet. Many of the present designs do not provide a tab or free end that is easily accessible for all patients, including those with limited dexterity. Many of the present designs require a sufficient amount of agility to easily peel away the free area.

Thus, there is a need for an effective laminate seal against moisture and/or light that may be safely and manually removed by the user, including those having limited dexterity.

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There is a further need for a blister pack having an easy means of removing the seal which will enable patients with limited dexterity to remove the seal without damaging the contents.

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There is also a further need for a blister pack design that does not require physical separation of the blister compartments prior to removal of the seal.

SUMMARY OF THE INVENTION

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The present invention is a packaging having a tray having at least one recess to receive contents therein and an upper layer, the packaging also having a manually removable sheet fixed in part to the upper layer of the tray and unfixed in part to the tray, the unfixed part of the sheet being in the form of a tab, the tab being located adjacent to one corner of the upper portion of the tray that forms the recess, whereby when the sheet is fixed to the tray it is an effective seal against moisture and light. The present invention further includes packaging having a peel off layer that may be manually removed for those with limited dexterity. The present invention also includes a tab having a graduated width for easy grasping by the patient. The present invention further provides for a tray that does not need to be separated into subsections prior to removal of the contents therein.

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The claims 2 to 5 describe preferred embodiments.

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BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims and accompanying drawings where:

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Figure 1 is a plan view of a first embodiment of the present invention;
Figure 2 is a section view along line A-A of the embodiment of Figure 1;
and
Figure 3 is a plan view of a second embodiment of the present invention.

DESCRIPTION OF THE INVENTION

The invention 10 is directed to a packaging system having a tray 12.

5 The tray 12, shown in Fig. 2, has a series of separated, spaced apart sections 11, shown in Fig. 1. Each section has a recess 14 therein as shown in Figure 1. The recesses are sized to accommodate a particular size tablet or capsule or a combination of both or other solid pharmaceutical dosage form. The tray 12 also has an upper surface 13. Once the solid pharmaceutical dosage forms are placed in the tray 12, a thin, flexible sheet 16 is fixed in part to the upper surface 13 of the tray 12. This may be accomplished by the use of adhesive or heat sealing. Once the heat sealing or application of adhesive is completed, there is an adhesive layer 17 located between the upper layer 13 of the tray 12 and the sheet 16.

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The tray 12 also has a series of perforations or cuts 18 to enable it to separate into smaller trays or single compartments. In addition, there are tabs 20 formed from a portion of the sheet that is not sealed to the upper layer. These are also shown in Figure 1 and may vary in shape and size depending upon the particular tablet, capsule or other solid dosage form being packaged in the tray 12. The tab 20 as shown, is graduated in width. The narrow tip 22 of the tab 20 enables a patient to easily separate the tab from the unsealed upper surface 13 of the tray 12. The increased width 24 of the tab 20 adjacent to the sealed upper surface 13 of the tray 12 aids the user in effectively peeling the tab and sealed sheet 16 away from the sealed upper surface of the tray. The tab 20 is located in one corner of the section 11 so that the user does not need to separate the sections of the tray 12 prior to peeling the tab away from the tray. In addition, the tabs 20 may be cut in a number of different ways to ease manufacturing time and minimize materials.

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The sheet is effectively able to seal against moisture and light and enables a user to manually peel off the layer with ease without the need for scissors or any other sharp object and while accessing the contents in an undamaged form. It is preferred that the sheet thickness is between 15 and 60 microns. An example of the sheet is an extruded aluminum film provided by Burgopack - Italy film # 25PA-45-PVC60. Alternatively there are unextruded foils that may be applied using adhesive.

35

It is also noted that while Figure 1 discloses a first embodiment of the present invention there are other ways of arranging the compartments and the tabs so as to maintain ease of use by the user but also to make manufacturing as easy and as inexpensive as possible. Another embodiment of the invention having curved shaped tabs 22 is set forth in Figure 3.

While preferred embodiments of the present invention has been depicted and described, it will be appreciated by those skilled in the art that many modifications, substitutions and changes may be made thereto without department from the true spirit and scope of the invention.

CLAIMS

What is claimed is:

- 5 1. A packaging comprising:
 a tray having a series of spaced apart sections, each section having a
 recess and an upper surface;
 a sheet fixed in part to the upper surface of the tray having at least a
 portion of the upper surface of the tray not fixed to the tray thereby creating a
10 tab, the tab being graduated in width from a narrow tip to a wider base, the
 base being adjacent to the sealed portion of the sheet, and the tab being
 located in one corner of the section of the tray.
2. The packaging of Claim 1 wherein the recesses are between 0.5
15 and 50 mm in diameter.
3. The packaging of Claim 1 wherein the sheet is an aluminum
 laminate.
- 20 4. The packaging of Claim 1 wherein the sheet has a range of
 thickness from between 15 and 60 microns.
5. The packaging of Claim 1 wherein the sheet is fixed to the tray by
 means of heat sealing.

Fig. 1

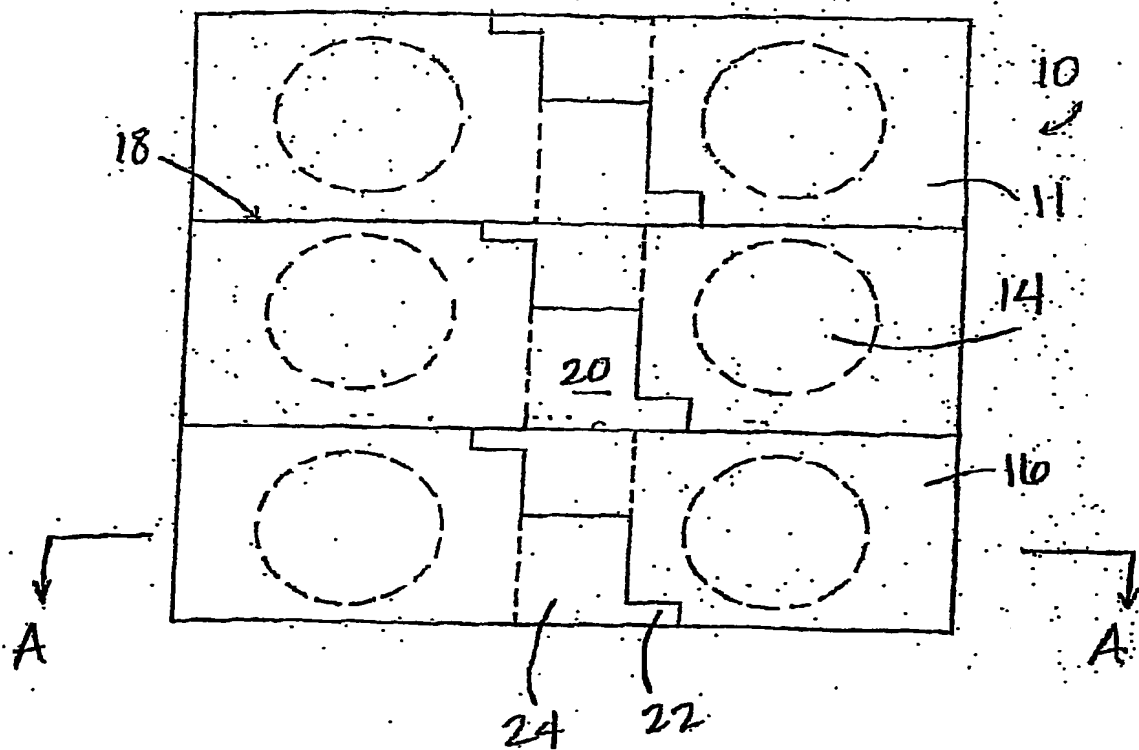
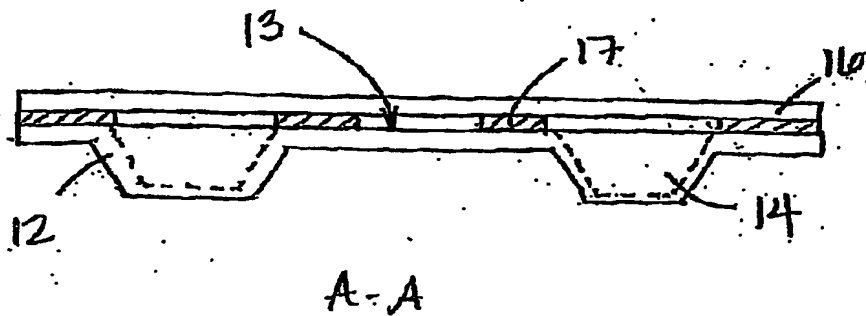


Fig. 2



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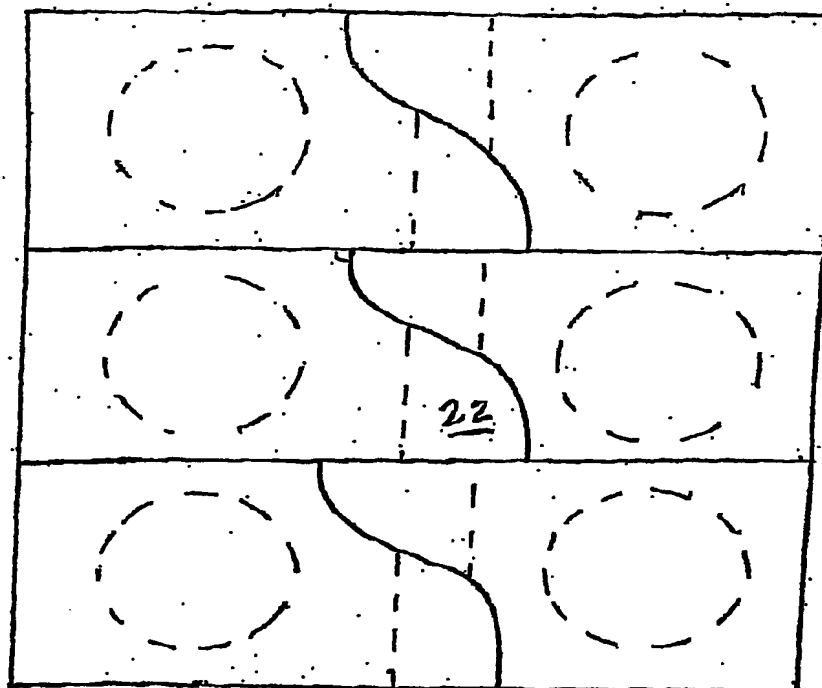


Fig. 3

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 B65D75/32 B65D75/34 B65D75/58

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 101 02 818 A (LOHMANN THERAPIE SYST LTS) 8 August 2002 (2002-08-08)	1,2
A	the whole document	3-5
X	US 6 155 423 A (JONES BRIAN ET AL) 5 December 2000 (2000-12-05)	1,3-5
	the whole document	
X	DE 88 11 951 U (LOBERMEIER HANS) 12 January 1989 (1989-01-12)	1
	the whole document	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.*** Special categories of cited documents :**

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 10102818	A	08-08-2002	DE 10102818 A1	08-08-2002
			WO 02059012 A1	01-08-2002
			EP 1353857 A1	22-10-2003
<hr/>				
US 6155423	A	05-12-2000	AU 732118 B2	12-04-2001
			AU 6792298 A	22-10-1998
			CA 2284132 A1	08-10-1998
			EP 1015352 A1	05-07-2000
			JP 2001518862 T	16-10-2001
			WO 9843893 A1	08-10-1998
<hr/>				
DE 8811951	U	12-01-1989	DE 8811951 U1	12-01-1989
<hr/>				